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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/814,257

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Nancy D. Hanson

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05/19/2003

MUETING, RAASCH & GEBHARDT, P.A.

P.O. BOX 581415

MINNEAPOLIS, MN 55458

EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,257

Applicant(s)

HANSON ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE filed on January 27, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17, 39-44, 47-49 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-16 and 51 is/are allowed.
- 6) ☒ Claim(s) 17, 39-44, 47-49, 52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 27, 2003 and the amendment filed on December 10, 2002 have been entered. The claims pending in this application are claims 12-17, 39-44, 47-49, and 51-53. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on December 10, 2002.

Claim Objections

2. Claim 53 is objected to because of the following informality: the phrase "the OXA family beta-lactamase enzymes designated as OXA-10, 11, or 14" should be "the OXA family beta-lactamase enzymes designated as OXA-5, 6, 7, 10, 11, 13, or 14" since SEQ ID No: 38 and SEQ ID: 39 can be used to amplify OXA-5, 6, 7, 10, 11, 13, or 14 beta-lactamase enzymes in view of original filed claims 43 and 44.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17, 39-44, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although the specification describes OXA-1, 2, 3, 5-7, and 9-15 (for example, see specification, last paragraph of page 3), the specification does not adequately describe that OXA-16 and 17 as recited in claims 17, 39-44, and 49. MPEP 2163.06 states that "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." In view of the embodiments adequately description in the specification, the subject application does not reasonably convey to one skilled in the art that applicant was in possession of the full scopes of products encompass in the claims at the time of the application was filled. Therefore, the written description requirement has not been satisfied.

In support of this position, attention is directed to the decision of *Vas-Cath inc. V. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

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Response to Arguments

In page 6, third paragraph of applicant's remarks filed on December 10, 2002, applicant argues that "[C]laims 17 and 49 have been amended to recite primers specific for nucleic acid characteristic of OXA family beta lactamase enzymes excluding OXA-1, 10, 11, 14, 16 and 17. Claim 43 has been amended to recite primers specific for nucleic acid characteristic of OXA-5, 6, 7 and 13 beta lactamase enzymes. Applicants respectfully assert that by reciting a subgenus of the OXA family in these claims (e.g., by excluding the prior art. Applicants are not claiming new matter. Application of Johnson, 55 F.2d 1008, 1019 (1977) (Appendix B)."

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Although the examiner agrees with applicant that the wording "excluding" can be used in claims 17 and 49 to exclude the prior art rejections, since the specification does not adequately describe that OXA-16 and 17 as recited in claims 17, 39-44, and 49, newly added phrase "excluding OXA-1, 10, 11, 14, 16 and 17" raises the issue of new matter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17, 39-44, 47, 48, 52, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 17, 52, and 53 are rejected as vague and indefinite in view of the phrase "wherein one primer of the pair is complements to at least a portion of the beta-lactamase nucleic acid in

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the sense strand and the other primer of each pair is complementary to at least a portion of the beta-lactamase nucleic acid in the antisense stand” because it is unclear that “the pair” and “each pair” in the phrase are directed to the same pair of oligonucleotide primer or not. If “the pair” and “each pair” in this phrase are directed to the same pair of oligonucleotide primers, the examiner suggests applicant to change “each pair” to “the pair” in order to make the first part of the phrase corresponds to the second part of the phrase.

8. Claims 17, 52, and 53 are rejected as vague and indefinite in view of the phrase “ wherein each extension product after separation from the beta-lactamase nucleic acid serves as a template for the synthesis of an extension product for the other primer of each pairs” because it is unclear what the phrase means. Since it is known that, during the PCR, each extension product after separation from its complementary strand (its template) serves as a template for the synthesis of another extension product in later cycles using a primer that is complementary to each extension product, the phrase “the other primer of each pair” in claims 17, 52, and 53 are not clear enough for one skilled artisan to understand claimed invention. The examiner suggests applicant to change the phrase “for the other primer of each pairs” to “using a primer that is complementary to each extension product”.

9. Claim 44 is rejected as vague and indefinite in view of claim 17, original filed claim 43 (see claim 43 filed on November 14, 2001) and newly added claim 53 because claim 17 and claim 44 are not correspond each other and claim 44 does not further limit claim 17. Since claim 17 is directed to the primers that are specific for nucleic acid characteristic of the OXA family of beta-lactamase enzymes excluding OXA-1, 10, 11, 14, 16, and 17, primers in its dependent claims

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including claim 44 should not anneal to nucleic acid characteristic of the OXA-1, 10, 11, 14, 16, and 17 beta-lactamase enzymes. However, since original filed claim 43 is directed to the primers that are specific for nucleic acid characteristic of the OXA-5, 6, 7, 10, 11, 13, and 14 beta-lactamase enzymes and claim 44 is dependent on claim 43, in fact, the primers in claim 44 (SEQ ID NO: 38 and SEQ ID NO: 39) are specific for nucleic acid characteristic of the OXA-5, 6, 7, 10, 11, 13, and 14 beta-lactamase enzymes. This conclusion is further confirmed by claim 53 wherein SEQ ID NO: 38 and SEQ ID NO: 39 as recited in claim 44 are the primers that are specific for the OXA-10, 11, or 14. Therefore, the primers in claim 44 (SEQ ID NO: 38 and SEQ ID NO: 39) are not specific for nucleic acid characteristic of the OXA-5, 6, 7, or 13 beta-lactamase enzyme since, in view of original filed claim 43 and newly added claim 53, the primers in claim 44 can also be used to amplify OXA-10, 11, and 14. Claim 17 and claim 44 are not correspond each other and claim 44 does not further limit claim 17. Please clarify.

Conclusion

10. The references from Vahaboglu *et al.*, (J. Clin. Microbiology, 36, 827-829, March 1998) and Siu *et al.*, (APMIS, 106, 917-920, September 1998) should not be used to reject claims 17 and 49 under 35 USC 102 or 35 USC 103 because the primers taught by Vahaboglu *et al.*, can be used for amplifying OXA-7, 10, 11, 13, 14, 16, and 17 and the primers taught by Siu *et al.*, can be used for amplifying OXA-1 and 4 while claims 17 and 49 requires that primers are specific for nucleic acid characteristic of the OXA family of beta-lactamase enzymes excluding OXA-1, 10, 11, 14, 16, and 17.

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11. Claims 12-16 and 51 are allowed since SEQ ID Nos: 34-43 are free of prior art.
12. Claims 52 and 53 appears to be allowable if applicant can overcome the rejection under 35 USC 112, second paragraph.
13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.



Frank Lu
May 15, 2003